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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/079,874	05/15/98	BILLING-MEDEL	P	6106.US.P1

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EXAMINER	
CANELLA,K	
ART UNIT	**PAPER NUMBER**
1642	13

DATE MAILED: 11/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/079,874	Billing-Medel
Examiner	**Group Art Unit**
Karen Canella	1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3 months* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-9 and 17-19* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-9 and 17-19* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Amendment

1. Please note that the examiner to which your application is assigned at the PTO has changed.
2. Claims 1-6 and 17 have been amended. Claims 1-9 and 17-19 are under consideration.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn

4. The rejection of claims 1-9 and 17-19 under 35 U.S.C. 101, because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility is withdrawn in light of applicants arguments with reference to exhibit A.

Claim Rejections Maintained

5. The rejection of claims 17-19 under 35 U.S.C.112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to which it pertains, or with which it is most nearly connected , to use the invention, is maintained for reasons of record. Applicant argues that the target polynucleotide has been found to encode PSCA which is over expressed in prostate cancer. Claims 17-19 are drawn to a method of detecting urinary tract disease. The specification describes the isolation of these sequences from a combination of healthy and diseased urinary tract tissue and there is no evidence of record that the detection of these polynucleotide sequences is indicative of the presence of urinary tract disease. Applicant argues that the SEQ ID NO:1-12 are found in 78.5% of urinary tract tissue libraries and in only 4.2% of other non-urinary tract tissue libraries. Applicant further argues that the claimed urinary-specific polynucleotides, SEQ ID NO:1-12, are useful in the diagnosis of diseases caused by hypertrophic proliferation. This is not found persuasive. The specification discusses the isolation of SEQ ID NO:1-12 from cDNA libraries derived from both normal and diseased urinary tract tissues and there are no examples or teachings in the specification that

would indicate that normal urinary tract tissue does not express the polynucleotides of SEQ ID NO:1-12. The specification does not show any examples linking the diagnosis of a hypertrophic proliferation state such as neoplasia in the urinary tract or cancer of the urinary tract with the presence of the claimed polynucleotides. There is no teaching correlating the detection of SEQ ID NO:1-12 with metastatic urinary tract cancer. The specification does not teach polynucleotides consisting of SEQ ID NO:1-12 as serum markers for urinary tract cancers. In light of the above reasons, one of skill in the art would be forced into undue experimentation to use the polynucleotides of the instant invention for the detection of urinary tract disease with a reasonable expectation of success.

New Claim Rejections

6. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides having 100% identity to SEQ ID NO:1-12 and complements thereof, does not reasonably provide enablement for polynucleotides having 70% identity to SEQ ID NO:1-12 . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method of detecting target in a test sample comprising contacting the test sample with a specific polynucleotide or complement thereof and determining the presence of said target polynucleotide wherein said specific polynucleotide has at least 70% identity to SEQ ID NO:1-12. Thus, the claims are drawn to non disclosed polynucleotide "variants" of SEQ ID NO:1-12. The specification defines only SEQ ID NO:1-10 as EST sequences derived from cDNA libraries, SEQ ID NO:12 as the "consensus" sequences formed by the overlap of SEQ ID NO:1-10, and SEQ ID NO:11 as the "full length" sequence encoded by the cumulative EST sequences.. Since there is no limitation other than 70% sequence identity, it is assumed for examination purposes that "variants" of polynucleotides include substitutions, insertions and deletions of nucleic acid residues that will result in altered polynucleotides. One

cannot extrapolate the teaching of the specification to the scope of the claims because, when given the broadest reasonable interpretation, the claims are clearly intended to encompass all species of polynucleotides that encode numerous proteins and peptides, the overwhelming majority of which have neither structural nor functional identity with SEQ ID NO:1-12 and no guidance has been given as to how to use these"variant" species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims since the specification gives no guidance on or exemplification of how to use the broadly claimed polynucleotides that would encode a broad genus of polypeptides. Protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, replacement of a single lysine residue at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein. Burgess et al. (J of Cell Bio. 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen. Lazar et al. Molecular and Cellular Biology 8:1247-1252 (1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein. Clearly, it could not be predicted that a polynucleotide variant, differing by 30% from SEQ ID NO:11 or 12, would encode a protein that would even be a prostate antigen or a prostate antigen that is over expressed in prostate cancer. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to use polynucleotide variants having as little as 70% sequence identity to SEQ ID NO:1-12. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of Accession numbers AA389615 or N32614 or N32011 or H02338 or H96372. In light of Maniatis (2nd edition, 1989, p. 7.39). Claim 1 is drawn to the detection of a target sequence using specific polynucleotides having at least 70% identity with a polynucleotide selected from the group consisting of SEQ ID NO:1-12. Accession Number AA389615 is a polynucleotide having 72.1% and 71.6% identity to SEQ ID NO:2 and 3, respectively. Accession Number N32614 is a polynucleotide having 97.0% identity to SEQ ID NO:11. Accession Number N32011 is a polynucleotide having 95.7% and 97.2% identity to SEQ ID NO:7 and 12, respectively. Accession Number HO2338 is a polynucleotide having 95.1% identity to SEQ ID NO:6. Accession Number H96372 is a polynucleotide having 99.6% identity to SEQ ID NO:9. The Accession numbers do not teach a method for detecting the presence of a target polynucleotide comprising contacting a specific polynucleotide having 70% identity to SEQ ID NO:1-12.

However, the disclosed sequences represent polynucleotide sequences having greater than 70% identity to SEQ ID NO:2, 3, 7, 9, 10, and 12. Maniatis teaches the use of specific polynucleotides for probing target polynucleotides. It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to use any of Accession numbers AA389615 or AA446964 or AA543070 or N32614 or N32011 or H02338 or H96372 as specific polynucleotides in a method to detect a target sequence having 70% identity to SEQ ID NO:1-12. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Maniatis on the use of double-stranded DNA labeled via nick translation (the specific polynucleotide) for the detection of RNA (the target polynucleotide).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
November 6, 2000

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